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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/031,087	02/26/1998	CHIH-SHENG CHIANG	054769-2001	8207

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FOLEY & LARDNER LLP
P.O. BOX 80278
SAN DIEGO, CA 92138-0278

EXAMINER	
TUNG, JOYCE	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/031,087	CHIANG ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-11 and 14-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-11 and 14-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/20/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed 7/20/06 to the Office action has been entered. Claims 2-11, and 14-22 are pending.

1. The rejection of claim 3-6, 8-10, 20 and 22 under 35 U.S.C. 102(e) as being anticipated by Heller et al. (5,849,489, issued December 15,1998) is withdrawn because of the argument.

2. The rejection of claims 2, 11 and 21 under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (5,849,489, issued December 15,1998) as applied to claims 3-6, 8-10, 20 and 22, further in view of Morrison et al. (Analytical Biochemistry, 1989, Vol. 183, pg. 231-244) is withdrawn because of the argument.

3. The rejection of claims 14-18 under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (5,849,489, issued December 15,1998) as applied to claims 3-6, 8-10, 20 and 22, further in view of Hiroaki et al. (EP 0461 863 A1) is withdrawn because of the argument.

4. The rejection of claim 7 under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (5,849,489, issued December 15,1998) as applied to claims 3-6, 8-10, 20 and 22 above, and further in view of Meade et al. (See 5,824,473, issued October 20, 1998) is withdrawn because of the argument.

5. The rejection of claim 19 under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (5,849,489, issued December 15,1998) as applied to claims 3-6, 8-10, 20 and 22, further in view of Walker et al. (5,270,184) is withdrawn because of the argument.

THE NEW GROUNDS OF REJECTIONS

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 2-11, and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tyagi et al. (6,103,476, issued Aug. 15, 2000), in view of Diamond et al. (4,766,062, issued Aug. 23, 1988).

Tyagi et al. disclose assays for monitoring the progress of an amplification reaction. The probe can be present during synthesis. The presence of the probes improves the accuracy of the estimates of the target nucleic acid concentration (See column 22, lines 41-46 and lines 57-61). Other nucleic acid amplification schemes can be monitored, such as strand-displacement amplification (See column 23, lines 36-41). The polymerase is thermostable (See column 34, lines 60-67).

Tyagi et al. do not disclose the probe, which has the features, recited in claims 20, 22, and 3-10.

Diamond et al. disclose a diagnostic reagent containing a complex of a probe (See the Abstract). The probe has the same features as recited in claims 20, 22, and 3-10 (See column 6, lines 3-19, column 21, lines 15-52).

One of the ordinary skill in the art would have been motivated to apply the complex of the probe of Diamond et al. because as indicated by Diamond et al. the complex of the probe is used in solution as the reagent is mixed with a biological sample such that hybridization will occur (See column 7, lines 57-67) since monitoring nucleic acid amplification is always occurred in solution and the labeled polynucleotide is stable, but reversible binding to the probe at a specific locus and has a label susceptible to detection, especially after displacement (See column 8, lines 55-60). It would have been prima facie obvious to apply the complex of the probe as taught by Diamond et al. for monitoring nucleic acid amplification.

8. Claims 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tyagi et al. (6,103,476, issued Aug. 15, 2000), in view of Diamond et al. (4,766,062, issued Aug. 23, 1988) as applied to claims 2-11, and 19-22, further in view of Hiroaki et al. (EP 0461 863 A1).

The teachings of Tyagi et al. and Diamond et al. are set forth in section 7 above. Tyagi et al. and Diamond et al. do not disclose that the target polynucleotide comprises hepatitis C virus genome, the probe has the sequence of SEQ ID NO: 3 and 4 and the primer has the sequence of SEQ ID NO: 1 and 2.

Hiroaki et al. disclose a highly sensitive detection system for NANB hepatitis virus at its gene level and oligonucleotide primer used for the system (See pg. 2, lines 31-32). The NANB hepatitis is termed hepatitis C virus (HCV) (See pg. 2, lines 10-12). A nucleotide sequence of

the 5' noncoding region from HC-J1 has been identified (See pg. 3. lines 4-32). The primers used in the highly sensitive detection system for HCV corresponding to the part of the 5' noncoding region of HCV are disclosed (See pg. 3, lines 38-42). The nucleotide of the 5' noncoding region comprises SEQ ID NO: 1 and 3 and the complementary sequence of SEQ ID NO 2 and base pair 1-17 of SEQ ID NO: 4 (See pg. 7, lines 11-21 and pg. 8, lines 15-19).

One of ordinary skill in the art would have been motivated to apply these nucleic acid sequences disclosed by Hiroaki et al. as probes and primers in the method of Tyagi et al. for the specific detection of the target polynucleotide, hepatitis C virus because these nucleic acid sequences provide a highly sensitive detection system for NANB hepatitis virus at its gene level (See pg. 2, lines 31-32). It would have been prima facie obvious to apply SEQ ID NO: 1 and 2 as primers and SEQ ID NO: 3 and 4 as probes in the method of ~~Heller~~ Tyagi et al. for the detection of the target polynucleotide, hepatitis C virus.

Summary

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung J. T.
September 29, 2006

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
10/2/06